



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-0950]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) is submitting the information collection request titled "The National Health and Nutrition Examination Survey (NHANES)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on November 21, 2022 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the

burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB Control No. 0920-0950, Exp. 04/30/2023) - Extension - National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

The National Health and Nutrition Examination Survey (NHANES) is designed to study the relationship between diet, nutrition, and health in a representative sample of the civilian, non-institutionalized population of the United States. Information collection involves a variety of modes and sources including physical examinations, laboratory tests, and interviews. Findings are used to produce descriptive statistics that measure the health and nutrition status of the general population, generate national reference data on height, weight, and nutrient levels in the blood, and monitor the prevalence of chronic conditions and risk factors for those conditions.

The NHANES was conducted periodically between 1970 and 1994 and has been conducted continuously since 1999 by the NCHS, CDC,

in collaboration with a variety of agencies that sponsor specific components of NHANES. To manage participant burden and respond to changing public health research needs, NCHS cycles in and out various components, however, the study design generally allows results from more recent NHANES to be compared to findings reported from previous surveys. NCHS collects personally identifiable information (PII) to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services. Participant-level data items include basic demographic information, name, address, Social Security Number, Medicare number and participant health information.

Data collection for the 2021/2022 cycle of NHANES began in August 2021. The 2021/2022 NHANES physical examination includes the following components: anthropometry (all ages), liver elastography (ages 12 and older), standing balance (ages 20-69), 24-hour dietary recall via phone (all ages), blood pressure measurement (ages eight and older), and dual X-ray absorptiometry (DXA) (ages 8-69, total body scan). While at the examination center, additional interview questions are asked of participants and a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later. The bio specimens collected for laboratory tests include urine and blood. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. Consent to store DNA is continuing in NHANES.

Beginning in 2021, NHANES added the following laboratory tests: Acetylcholinesterase Enzyme Activity in whole blood; an Environmental Toxicant in Washed Red Blood Cells (Hemoglobin Adducts); Environmental Toxicants in serum (seven terpenes); Environmental Toxicants in urine (seven volatile organic compound (VOC) metabolites); Infectious Disease Markers in serum (Enterovirus 68 (EV-D68) and Human Papilloma Virus (HPV) in serum); Nutritional Biomarkers in plasma (Four trans-fatty acids (TFA)); and two Nutritional Biomarkers in serum. Additionally, at the start of the 2021 survey year, the following Laboratory Tests were modified: Steroid hormones in serum (eleven steroid hormones).

NHANES components that were cycled out in 2021-22 are the Blood Pressure Methodology Study and laboratory tests of Adducts of Hemoglobin (Acrylamide, Glycidamide) and Urine flow rate.

Most sections of the NHANES interviews provide self-reported information to be used in combination with specific examination or laboratory content, as independent prevalence estimates, or as covariates in statistical analysis (e.g., socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition-monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and

weight history/self-image/related behavior.

Burden for individuals varies based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults. This is because young people may have fewer health conditions or medications to report so their interviews take less time or because certain exams are only conducted on individuals 18 and older, etc. In addition, adults often serve as proxy respondents for young people in their families. Finally, the burden estimate for NHANES includes developmental projects that support the planning process for future cycles of information collection. Developmental projects may include activities such as tests of new equipment, crossover studies between current and proposed methods, test of different study modes, settings or technology, outreach materials, incentive strategies, sample storage and processing or sample designs.

The 2021/2022 cycle of NHANES includes a number of modifications necessitated by the ongoing COVID-19 pandemic, such as additional COVID-19 screening tests and procedures, additional laboratory content for COVID-19 serology, decreased use of in-person interviews, and increased use of telephone interviews and/or audio-computer assisted self-interview (ACASI). Selected data collection components were discontinued from the NHANES survey and physical exams in order to manage participant risk and burden. Some modifications were described in the Revision request for NHANES 2021/2022 and further

adjustments were incorporated through the Change Request mechanism.

The COVID-19 pandemic also resulted in operational delays. CDC therefore requests OMB approval to extend information collection for 18 months in order to complete the 2021/2022 NHANES as previously approved, with the COVID-19 modifications such as multi-mode screening and electronic consent procedures. The base sample will remain at approximately 5,000 interviewed and examined individuals annually. The yearly goal for interview, exam and post exam components is 5,600 participants. To achieve this goal, NHANES may need to screen up to 8,300 individuals annually. Participation in NHANES is voluntary and confidential. There is no cost to respondents other than their time. The total estimated annualized burden is 65,630 hours.

Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per respondent | Average Burden per Response (in hours) |
|---------------------------|---|-----------------------|------------------------------------|--|
| Individuals in households | Screenener | 8,300 | 1 | 10/60 |
| Individuals in households | Household Interview | 5,600 | 1 | 1 |
| Individuals in households | MEC Interview & Examination | 5,600 | 1 | 2.5 |
| Individuals in households | Telephone Dietary Recall & Dietary Supplements | 5,600 | 1 | 1.3 |
| Individuals in households | Flexible Consumer Behavior Survey Phone Follow-Up | 5,600 | 1 | 20/60 |
| Individuals in households | Developmental Projects & Special Studies | 3,500 | 1 | 3 |
| Individuals in households | 24-hour wearable device projects | 1,000 | 1 | 25 |

Jeffrey M. Zirger,
*Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.*

[FR Doc. 2023-04493 Filed: 3/3/2023 8:45 am; Publication Date: 3/6/2023]